

### **REMARKS**

Claims 7-15 are pending in the present application. Claims 1-6, 9 and 10 have been cancelled without prejudice or disclaimer. Claim 15 has been withdrawn as being directed to non-elected subject matter. Claims 7, 8 and 11-15 have been amended.

Applicants, by canceling or amending any claims, make no admission as to the validity of any rejection made by the Examiner against any such claims. Applicants reserve the right to reassert any of the claims canceled and/or the original claim scope of any claim amended, in a continuing application.

Claim 1 has been amended to recite a "patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100  $\mu\text{m}$ , the multilayer film comprising an innermost layer having a polyacrylonitrile surface for contact with a patch, the patch comprising a pressure-sensitive adhesive layer laminated on at least one side of a support and has a release film attached to the pressure-sensitive adhesive layer, the pressure-sensitive adhesive layer containing a drug represented by general formula (1) [formula omitted] or a pharmaceutically acceptable salt thereof, wherein R represents 2-isopropoxyethoxymethyl, carbamoylmethyl or 2-methoxyethyl." Support for this amendment can be found throughout the specification and claims as originally filed. For example, please see the present specification at paragraph [0031] and cancelled claim 9.

Claims 8 and 11-14 have been amended to be placed in proper US claim format. Claims 11 and 12 have been further amended to correct dependency in view of the amendments to claim 7 and cancellation of claims 9 and 10. Support for the

amendments to claims 8, and 11-14 can be found throughout the specification and claims as originally filed.

Claim 15 has been amended to recite a "method for inhibiting drug migration of a drug onto the inner surface of a pouch housing a patch, the method comprising: providing the pouch, the pouch comprising a multilayer film having a thickness of from 20 to 100  $\mu\text{m}$ , the multilayer film comprising an innermost layer having a polyacrylonitrile surface for contact with the patch; and storing the patch in the pouch, the patch comprising a pressure-sensitive adhesive layer and a release film attached to the pressure-sensitive adhesive layer, the adhesive layer containing the drug and being laminated on at least one side of a support, the drug being represented by general formula (1) [formula omitted] or a pharmaceutically acceptable salt thereof, wherein R represents 2-isopropoxyethoxymethyl, carbamoylmethyl or 2-methoxyethyl." Support for this amendment can be found throughout the specification and claims as originally filed. For example, please see the present specification at paragraph [0031] and cancelled claim 9.

No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

- I. At page 4 of the Official Action, claims 7-12 have been rejected under 35 USC § 103(a) as being unpatentable over Kanios (US Patent No. 6,905,016) in view of JP 2003-303122 ("JP '122"), or vice versa JP '122 in view of Kanios et al.***

The Examiner asserts that it would have been obvious to provide a package for transdermal system comprising an innermost layer of acrylonitrile and outermost

layer of polyethylene terephthalate as allegedly taught by Kanios to deliver bisoprolol in adhesive as allegedly taught by JP '122.

Applicants note that the rejection of claims 9 and 10 has been obviated by the cancellation thereof. Accordingly, reconsideration and withdrawal of the rejection of claims 9 and 10 is respectfully requested.

In view of the following, Applicants respectfully traverse the rejection of claims 7, 8 and 11-14.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." See *KSR International Co. v. Teleflex Inc. et al.*, 550 U.S. 398 at 417-418. Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from

the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

It is submitted that a proper case of *prima facie* obviousness has not been established because whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter, as required by *In re Wilson*. In addition, Applicants submit that the presently claimed subject matter is unexpectedly superior over the cited art for at least the reason that the presently claimed pouch has a thickness of about 10 to 62 times less than the pouches in the cited art, but is still an effective storage system for a patch containing an active ingredient, which has superior gas permeability and manageability.

Independent claim 7 is directed to a patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100  $\mu\text{m}$ , the multilayer film comprising an innermost layer having a polyacrylonitrile surface for contact with a patch, the patch comprising a pressure-sensitive adhesive layer laminated on at least one side of a support and has a release film attached to the pressure-sensitive adhesive layer, the pressure-sensitive adhesive layer containing a drug represented by general formula (1) [formula omitted] or a pharmaceutically acceptable salt thereof, wherein R represents 2-isopropoxyethoxymethyl, carbamoylmethyl or 2-methoxyethyl. (Emphasis Added). Claims 8 and 11-12 depend, either directly or indirectly, from claim 7.

In contrast, Applicants submit that Kanios is directed to a propanolol containing patch packaged in a pouch having a total thickness of about 1000 to 6250  $\mu\text{m}$ . See Kanios, generally. In addition, JP '122 merely describes bisoprolol containing patch.

However, whether taken alone, or in combination, none of the cited references teach or suggest ***a patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100  $\mu\text{m}$*** , as recited in claim 7. In this regard, Applicants note that only Kanios describes a pouch at all. In contrast to the presently claimed pouch, the pouch described by Kanios has a thickness ranging from 10 to 62 times greater than the thickness of the multilayer film of the presently claimed pouch. Applicants submit that neither Kanios, nor the skilled artisan at the time of invention of the presently claimed subject matter, conceived or considered making a pouch having the presently claimed thickness for containing a patch with the presently claimed structure. Any assertion to the contrary could only be made with hindsight, in view of the present specification and claims.

For the Examiners convenience, Applicants provide herein below a Table summarizing the vast differences in pouch thickness between the pouch presently claimed and described in the present specification, with the pouch described in Kanios.

[Table 1]

	Presently Claimed Pouch	Kanios	JP '122
Primary layer	20-100 $\mu\text{m}$ (paragraph [0031] of the present specification)	0.5-2.5 mm (column 6, line 35)	n/a
Secondary layer		0.2-3.0 mm (column 6, line 48)	n/a
Adhesive layer		0.3-0.75 mm (column 7, line 40)	n/a
<b>Total thickness</b>	20-100 $\mu\text{m}$	1.0-6.25 mm (1000-6250 $\mu\text{m}$ )	n/a
Example	40 $\mu\text{m}$ (paragraph [0051] of the present specification)	About 1.25-3.25 mm (Examples 1-14)	n/a

As evidenced by Table 1, Applicants respectfully submit that the presently claimed pouch thickness is not taught or suggested by Kanios or JP '122.

In addition to the great difference in pouch thickness, Applicants respectfully submit that the presently claimed subject matter exhibits superior gas permeability which is derived from the combination of the structure of the claimed pouch with the patch enclosed therein, the patch having the claimed structure and active ingredient. As evidence of this Applicants respectfully direct the Examiners attention to paragraph [0031] of the present specification, which provides that:

From the standpoint of gas permeability and manageability of the pouch, the thickness of the multilayer film 10a or 10b is preferably 20-100  $\mu\text{m}$ . ***A thickness of less than 20  $\mu\text{m}$  will lead to insufficient strength and may invite damage***, thus impairing the airtightness, ***while a thickness of greater than 100  $\mu\text{m}$  will impair the flexibility of the film***, possibly leading to poor manageability. (Emphasis Added).

Applicants respectfully submit that, in addition to not being obvious because every element is not taught or suggested by the cited art, the presently claimed subject matter is non-obvious due to unexpectedly superior gas permeability and

manageability exhibited.

In view of the foregoing, Applicants respectfully submit that, whether taken alone or in combination, nothing in the cited references render the presently claimed subject matter obvious within the meaning of 35 USC § 103. Accordingly, reconsideration and withdrawal of this rejection is respectfully submitted.

***II. At page 8 of the Official Action, claims 13 and 14 have been rejected under 35 USC § 103(a) as being unpatentable over Kanios (US Patent No. 6,905,016) in view of JP '122, as applied to claims 7-12 above, and in further view of JP 07-132946 ("JP '946").***

The Examiner asserts that it would have been obvious to add an aluminum foil layer to a multilaminate package having an innermost layer of acrylonitrile and outermost layer of terephthalate, as allegedly separately taught by Kanios, JP'122 and JP '946.

In view of the following, this rejection is respectfully traversed.

A brief outline of the relevant authority on obviousness is set forth above.

The presently claimed subject matter is also discussed in detail above with reference to independent claim 7. Applicants submit that claims 13 and 14 depend indirectly from claim 7.

In addition, each of Kanios and JP '122 are also discussed above.

As noted, whether taken alone or in combination, Kanios and JP '122 do not teach or suggest ***a patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100  $\mu$ m.***

Applicants respectfully submit that JP '946 does not remedy the deficiencies of Kanios and JP '122 because whether taken alone or together, none of the cited references teach or suggest **a patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100  $\mu\text{m}$** , as presently claimed.

In this regard, like JP '122, JP '946 also does not describe a pouch thickness at all. JP '946 is merely cited to show that aluminum may be utilized as a material in constructing housing material. Therefore, the additional description provided by JP '946 does not remedy the deficiencies of Kanios and JP '122.

In addition, Applicants once again note that the presently claimed subject matter is also non-obvious because it exhibits unexpectedly superior gas permeability and manageability, which is derived from the combination of the structure of the claimed pouch with the patch enclosed therein, the patch having the claimed structure and active ingredient. See, for example, paragraph [0031] of the present specification.

In view of the foregoing, Applicants respectfully submit that, whether taken alone or in combination, nothing in the cited references render the presently claimed subject matter obvious within the meaning of 35 USC § 103. Accordingly, reconsideration and withdrawal of this rejection is respectfully submitted.



**CONCLUSION**

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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